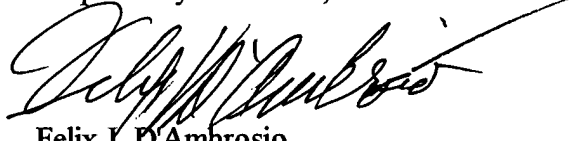


agree. The segments 20, 22, 24, 26, 28, 30, 32, 34 and 36 are part of the control layer 14 They all have equal thickness. They are "complementary in their peripheral configurations' (column 5, line 17-19). They are structurally different from the cushioned layers of the present invention. Compare Fig 3 of the present invention with Fig. 6a of Pendergast. The segments of Pendergast are uniform. Not so with the cushioning layers according to the present invention.

Two further papers are being submitted herewith which discuss the venous flow issue and resulting data in tabular form showing that the Venoped sole is superior.

The examiner is urged to take the above into consideration when considering this CPA..

Respectfully submitted,



Felix J. D'Ambrosio
Reg. No. 25,721

July 25, 2001

JONES, TULLAR & COOPER, P.C.
P.O. Box 2266 Eads Station
Arlington, Virginia 22202
(703) 415-1500



14.WORLD CONGRESS OF THE UNION INTERNATIONALE DE PHLEBOLOGIE

INFLUENCE OF SEVERAL FOOT-MUSCLE PUMP SUPPORTING DEVICES ON THE VENOUS FLOW VELOCITY DURING A SCHEDULED WALKING PROGRAM

H.Seiter 1) K.Bös2)

1)Seiter-Klinik, Wilhelmsplatz 11,70182 Stuttgart-Germany

2)Institut für Sport u.Sportwissenschaft/UNI Karlsruhe
Kaiserstr.12, 76128 Karlsruhe-Germany

Key words: venous flow rate, foot muscle pump, venous shoe insole, compression stocking, walking

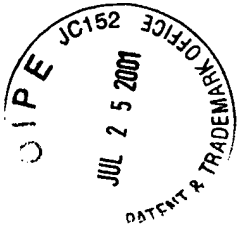
The main principle in the treatment of the chronic venous insufficiency is the augmentation of the venous flow velocity to reduce and/or prevent the well known problems resulting from the hypertonus of the peripheral veins. Walking which stimulates the foot muscle pump is the ideal sports activity for the veins. The sole of the foot consists of a tight and fine mesh-like network of veins which drain into the deep venous system and into the saphena magna and parva. During walking this foot muscle pump is squeezing this sponge-like network of these foot-sole veins and it comes to an acceleration of the venous flow velocity in the leg. We investigated the influence of a new muscle pump supporting device (shoe insole) on the venous flow rate in comparison with medical stockings of different categories(I,II)during a defined walking schedule with normal volunteers (Vena femor.superfic., Duplex technique, Woodway running-board).In the comparison without any supporting agent we found an acceleration of the venous flow velocity with this new developped shoe insole of 25-30%, with a compression stocking (I) of 20% and with a compression stocking (II) of 30%.

We conclude that this new shoe insole is an effective device to increase the venous flow velocity.

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Clinical studies

flow velocity in the Vena femoralis superficialis (cm/s)

| < rest > | < Walking (1 Min. 1,5 km/h, 1 Min. 2,0 km/h, 1 Min. 2,5 km/h, 1 Min. 3,0 km/h: → meas. |

Proband	(cm/s)	ohne Hilfsmittel (cm/s)	mit Venoped (cm/s)	mit K.Str. Klasse I (cm/s)	mit K.Str. Klasse II (cm/s)
m 1956	17	24	30	29	32
m 1931	21	30	37	34	38
w 1972	16	25	32	31	33
m 1935	11	17	23	22	22
w 1974	14	22	28	27	29
w 1978	23	36	42	43	47
w 1970	10	16	21	19	22
w 1951	9	15	22	20	21
w 1975	14	20	25	23	27
w 1964	12	18	22	21	24
		Ø 22,3	Ø 28,2	Ø 26,9	Ø 29,5
		= 100%	= 126,5%	= 120,6%	= 132,3%

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EUROPEAN VENOUS FORUM, 2ND MEETING**INFLUENCE OF SEVERAL FOOT-MUSCLE PUMP SUPPORTING DEVICES ON THE VENOUS FLOW VELOCITY DURING A SCHEDULED WALKING PROGRAM.****H. Seiter*, K. Boes*******Seiter-Klinik. Wilhelmsplatz 11. 70182 Stuttgart. **Institut für Sport u. Sportwissenschaft / UNI. Karlsruhe. Kaiserstr. 12. 76128 Karlsruhe. Germany.**

One of the most important principles in treatment of the chronic venous insufficiency is the increase of the venous flow velocity. Associated with physical reduction of venous capacity it will decrease and/or prevent the well known problems resulting from the hypertonus of the peripheral veins. Walking, which stimulates the foot and calf muscle pumps, is the ideal sports activity for the veins.

The sole of the foot consists of a tight and fine mesh-like network of veins and it comes to an acceleration of the venous flow velocity in the leg. Following our previous investigations on VENOPED where we have shown that our new shoe insole was able to accelerate the venous flow inside the femoral veins [Seiter H. Evaluation d'une nouvelle semelle veineuse.: VENOPED. XXXVème Congrès du Collège Français de Pathologie Vasculaire. J Mal Vasc 2001 26 (suppl. n° 1) : 1S55], we carried out an experiment to demonstrate a synergistic effect on the venous velocity when using the shoe insole and compression stockings class I and II (according to the European standard method of pressure measurement). We followed the same study design: vena femor. superfic. duplex measurement associated with Woodway running-treadmill on healthy volunteers. A defined walking schedule was outlined. We have found an acceleration of the venous flow velocity with this new combination with a synergistic effect ranged between 25 to 30% according to the different stockings categories.

We conclude that using VENOPED we reinforced the pumping activity of the lower leg while practising walking as a sport.

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Clinical studies

flow velocity in the Vena femoralis superficialis (cm/s)

| < rest > | < Walking (1 Min. 1,5 km/h, 1 Min. 2,0 km/h, 1 Min. 2,5 km/h, 1 Min. 3,0 km/h): → meas. |

Proband	(cm/s)	ohne Hilfsmittel (cm/s)	mit Venoped (cm/s)	mit K.Str. Klasse I (cm/s)	mit K.Str. Klasse II (cm/s)
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		Ø 22,3	Ø 24,0	Ø 23,9	Ø 29,5
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